MFI-35 (redacted copy)

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M5102n

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

01-PHI-03

WARNING LETTER

November 30, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Scott A. Warne, Owner
Medical Marketing & Management, L.L.C.
128 Riggle Street
Houston, PA 15342

Facility ID#: 223643

Dear Mr. Warne:

On November 27, 2000, an investigator from the Food and Drug Administration (FDA) visited your mammography facility located at Holiday Park Diagnostics, 21-I Sandune Drive, Pittsburgh, PA 15239 and collected information that revealed a serious regulatory problem. This site is presently accredited by the American College of Radiology (ACR) under the name of Allentown Diagnostics – Mobile 1, 701 E. Warrington Avenue, Pittsburgh, PA, with facility ID# of 223643. Under a Federal law, the Mammography Quality Standards Act of 1992 (MQSA), a mammography facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either 1) are being evaluated for accreditation by that body, or 2) have been accredited by that body are entitled to a certificate. The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility is qualified to perform quality mammography.

The mammography unit at Holiday Park Diagnostics was purchased from [redacted] in October 5, 1999. You informed the ACR of this transaction on October 13, 1999 and performed mammography under the FDA certificate issued to [redacted] under facility ID [redacted]. On December 16, 1999, the ACR informed you that this mammography unit was going to be issued a new ACR MAP# and that you would have to submit an accreditation application. At this point you were not permitted to perform mammography until you received a Provisional FDA Certificate. The Provisional FDA Certificate was not issued until February 3, 2000 and had an expiration date of August 3, 2000.

The evidence collected by the FDA shows that you have performed mammography without a valid FDA MQSA Certificate from December 16, 1999 through February 3, 2000. Our investigator found that the Holiday Park Diagnostics mammography facility performed mammography exams on the following days: 12/16, 17, 20, 21, 23, 27/1999; 1/4, 11, 13, 17, 18, 20, 21, 24/2000; and 2/1, 2, 3/2000. Approximately [redacted] patients were given mammography exams during this time period.

Performing mammography without a valid certificate is a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, assessing civil money penalties up to $10,000 or obtaining a court injunction against further mammography.

We acknowledge receipt of your letter dated September 26, 2000, which was sent in response to the one level 2 noncompliance observed during the annual MQSA inspection performed on September 6, 2000. This inspection found that the mammography equipment evaluation (by a medical physicist) of your [redacted] unit was not performed. This evaluation must be performed prior to using the mammography unit on patients. We acknowledge that a medical physicist survey of this unit was performed on December 20, 2000. We also acknowledge that the Holiday Park Diagnostics mammography unit is now fully accredited by the ACR under the name of Allentown Diagnostics – Mobile 1 and have a valid FDA Certificate with an expiration date of May 9, 2003.

Please inform this office in writing within fifteen (15) working days from the date you receive this letter, **of the specific steps you will take to assure that in the future your facility will only perform mammography examinations when you are in possession of a valid FDA MQSA Certificate.** Please submit your response to

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

Finally, you should understand that there are other FDA requirements pertaining to mammography. This letter only pertains to the issue of the performance of mammography under a valid FDA MQSA Certificate and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food & Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,

Cynthia J. Rakestraw

for Thomas Gardine
District Director
Philadelphia District

cc: Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Robert Scott
PA Dept. of Environmental Protection
Bureau of Radiation Protection
400 Waterfront Drive
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